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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,447	01/22/2002	James R. Keogh	P-9170.00	5485

27581 7590 04/10/2006

MEDTRONIC, INC.  
710 MEDTRONIC PARK  
MINNEAPOLIS, MN 55432-9924

EXAMINER
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HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/054,447

Applicant(s)

KEOGH ET AL.

Examiner

Casey Hagopian

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 1/18/2006.

### *Election/Restrictions*

2. The response to the election requirement filed 5/4/2005 will be maintained, however the examiner is requiring further a restriction of the pending claims because there are multiple inventions currently present in the application.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 233 and 273-281, drawn to a coated medical device and method of coating a hydrophilic polymer on a surface of a medical device, wherein the medical device has a catechol moiety disposed on the surface of the device and the hydrophilic polymer comprises a guanidino moiety, classified in class 424, subclass 422.
  - II. Claims 52-61, 234 and 282-290, drawn to a coated medical device and method of coating a hydrophilic polymer on a surface of a medical device, wherein the medical device has a guanidino moiety disposed on the surface of the device and the hydrophilic polymer comprises a catechol moiety, classified in class 424, subclass 422.
  - III. Claims 103-114, 235, 237-243, 246-249 and 291, drawn to a coated medical device and method of coating a biomolecule on a surface of a medical device, wherein the medical device has a hydrophilic polymer comprising a catechol moiety disposed on the surface of the device and

the biomolecule comprises a guanidino moiety, classified in class 424, subclass 422.

- IV. Claims 162-173, 236, 255-261, 264-267 and 292, drawn to a coated medical device and method of coating a biomolecule on a surface of a medical device, wherein the medical device has a hydrophilic polymer comprising a guanidino moiety disposed on the surface of the device and the biomolecule comprises a catechol moiety, classified in class 424, subclass 422.

4. The inventions are independent or distinct, each from the other because:

5. Inventions I-IV are directed to related products and processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are not capable of use together and they have materially different designs, modes of operation, functions and effects. Group I requires the catechol to be disposed on the surface of the device and then a polymer comprising a guanidino coated over the catechol. Group II requires the guanidino to be disposed on the surface of the device and then a polymer comprising a catechol coated over the guanidino. Group III requires the polymer comprising the catechol to be disposed on the surface of the device and then a biomolecule comprising a guanidino coated over the polymer. Group IV requires the polymer comprising the guanidino to be disposed

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on the surface of the device and then a biomolecule comprising a catechol coated over the polymer. As shown, each group includes different method steps and end products. The addition of a biomolecule in Groups III and IV such as a clotting agent would lend to a very different effect than the inventions of Groups I and II. Also, the placement of the polymer, whether it is on the surface of the device or disposed over top another agent will also lend to different effects. Likewise, the placement of the catechol and guanidino can effect whether they are released locally versus systemically and immediately versus sustained. For these reasons, each Group I-IV is an independent and distinct invention.

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

11. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Due to the complexity of the action, examiner submitted the Election Restriction in writing in lieu of calling applicant's attorney.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian  
Examiner  
Art Unit 1615

  
CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500

Continuation of Disposition of Claims: Claims pending in the application are 1-10,52-61,103-114,162-173,233-243,246-249,255-261,264-267 and 273-292.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-10,52-61,103-114,162-173,233-243,246-249,255-261,264-267 and 273-292.